PB86-135159

Guidance for the Reregistration of Pesticide Products Containing Norflurazon as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Dec 84

U.S. Department of Commerce
National Technical Information Service
NTIS

PB86-135159

GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS CONTAINING NORFLURAZON AS THE ACTIVE INGREDIENT

(GS-0229)

(105801)

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
ENVIRONMENTAL PROTECTION AGENCY
401 M STREET, SW.
WASHINGTON, DC. 20460
DECEMBER, 1984

REPRODUCED BY
NATIONAL TECHNICAL
INFORMATION SERVICE
U.S. DEPARTMENT OF COMMERCE
SPRINGFIELD, VA. 22161

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No.
PB86 135159/AS

4. Title and Subtitle
Guidance For The Reregistration Of Pesticide Products Containing Norflurazon As The Active Ingredient

5. Report Date
December, 1984

6.

7. Author(s)
EPA, Office of Pesticide Programs, Registration Division

8. Performing Organization Rept. No.
EPA-540/RS-84-024

9. Performing Organization Name and Address
US Environmental Protection Agency, Office of Pesticide Programs, Registration Division (TS-767C); 401 M Street, S.W., Washington, DC 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address
Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement
Freely available

19. Security Class (This Report)
unclassified

20. Security Class (This Page)

21. [illegible]es

22. Price

(See ANSI-Z39.18)

See Instructions on Reverse

OPTIONAL FORM 272 (4-77)
(Formerly NTIS-35)
Department of Commerce

NORFLURAZON PROJECT SUPPORT TEAM

Timothy Hunt	Office for Policy, Planning and Evaluation
Alice Wegman	Office of General Counsel
Patricia Ott	Exposure Assement Branch (HED)
Russel Farringer	Ecological Effects Branch (HED)
William Boodee	Residue Chemistry Branch (HED)
John Tice	Science Integration Staff (HED)
Carlos Rodriquez	Toxicology Branch (HED)
George Keitt	Science Support Branch (BUD)
Linda Teixiera	Program Coordination Staff (RD)
James Stone	Product Manager Team 23 (RD)

TABLE OF CONTENTS

Page

Introduction 1

I. Regulatory Position and Rationale. 4

II. Requirement for Submission of Generic Data 29

III. Requirement for Submission of Product-Specific Data 51

IV. Submission of Revised Labeling and Packaging Information. 56

A. Label Contents 56

1. Product Name 56
2. Company Name and Address 56
3. Net Contents 56
4. Product Registration Number. 56
5. Producing Establishment Registration Number. 57
6A Ingredient Statement 57
6B Pounds Per Gallon Statement. 57
7. Front Panel Precautionary Statements 57
7A Child Hazard Warning Statements. 57
7B Signal Word. 57
7C Skull and Crossbones and Word Poison 58
7D Statement of Practical Treatment 58
7E Referral Statement 58
8. Side/Back Panel Precautionary Labeling 58
8A Hazard to Humans and Domestic Animals. 58
8B Environmental Hazard 58
8C Physical or Chemical Hazard. 58
9 Misuse Statement 59
10A Storage and Disposal Block 61
10B Directions for Use 61

B. Collateral Information 61

V. Instructions for Submission. 62

APPENDICES

Page

II-1 Guide to Bibliography. 63

II-2 Bibliography. 65

II-3 FIFRA §3(c)(2)(B) Summary Sheet - EPA Form 8580-1 . . . 74

II-4 Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data EPA Form 8580-2. 76

III-1 Product Specific Data Report (End-Use Products). . . . 76

IV-1 40 CFR 162.10 Labeling Requirements. 78

IV-2 Table of Labeling Requirements 87

IV-3 Physical/Chemical Hazards Labeling Statement 91

IV-4 Storage and Disposal Instructions. 92

INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA sec. 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To carry out this task, we have established the Registration Standards program, which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. Based on the regulatory position, the Agency may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained in this Guidance Package but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that registrants submit data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing use product producers (basic suppliers of the active ingredient). However, end use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to cancel the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

You are reminded that FIFRA sec. 6(a)(2) requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM	ACTION(S) REQUIRED TO MAINTAIN REGISTRATION
I. Products That Do Not Qualify For The Formulator's Exemption	
A. Single Active Ingredient Products*	These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document.
B. Multiple Active Ingredient Products	These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required.
II. Products That Do Qualify For The Formulator's Exemption	Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices.

* End use products of registrants who also produce a manufacturing use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing use product(s). Such end use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing use products registered by any company end use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

I. REGULATORY POSITION AND RATIONALE

A. Introduction

This Registration Standard describes the regulatory position of the Environmental Protection Agency ("the Agency") based on an evaluation of the one manufacturing-use product (MP) with norflurazon as the sole active ingredient and the registered norflurazon uses. Future requests for registrations of substantially similiar products will be covered by this standard. Dissimilar products may be evaluated for registration. If registered, the standard will be amended accordingly. After briefly describing the chemical and its uses, this chapter presents the regulatory position and rationale, the criteria for registration, acceptable ranges and limits, labeling considerations and tolerance reassessment.

B. Description of Chemical

Norflurazon is the common name for 4-chloro-5-(methylamino)-2-(alpha, alpha, alpha-trifluoro-m-tolyl)-3-(2H)-pyridazinone as recognized by the American National Standards Institute. The trade names are Zorial®, Solicam® and Evital®. The Chemical Abstract Service Registry Number (CAS) is 27314-13-2 and the Agency's Chemical Code Number is 105801.

Norflurazon is a buff-white odorless crystalline solid. The melting point is 177 ± 3° C. The solubility of norflurazon at 25° C is 5 grams (g)/100 milliliters (ml) in acetone, insoluble in carbon disulfide, 14.2 g/100 ml in ethyl alcohol, 0.25 g/100 ml in xylol, and 28 parts per million (ppm) in water. The vapor pressure is less than (<) 1 x 10^{-5} Torr (25°C). Norflurazon is quite stable in dilute acidic or basic aqueous solution and storage stability is greater than 2 years.

Norflurazon is a selective preemergent herbicide to control germinating annual grasses and broadleaf weeds in certain crop and noncrop areas. Registered products are 97% active ingredient (a.i.) technical manufacturing-use-product, 80% a.i. wettable powder, 50% a.i. flowable, and 5% a.i. granular. Norflurazon is applied to the soil surface with application rates ranging from 0.5 to 8 pounds (lb.) active ingredient per acre. The rates depend on the soil type, with sandy clay or fine soils requiring the highest rate. Norflurazon is absorbed by the roots of weeds as they germinate and is translocated to the growing parts where it inhibits carotenoid biosynthesis resulting in chlorophyll photodegradation in susceptible species. On emergence from the soil, the weed seedlings turn white or pinkish, become necrotic and die.

C. Regulatory Position and Rationale

Based on a review and evaluation of all available data and other relevant information on norflurazon, the Agency has determined the following:

1. Existing data do not indicate that norflurazon will cause an unreasonable adverse effect to the environment.

Rationale: Available studies are adequate to evaluate toxicological effects of the pesticide. No toxicological effects were noted that require unique label statements or restrictions. A summary of the studies follows:

a. Norflurazon has a low toxicity (Category IV) based upon acute oral, dermal and inhalation effects, and is not a skin or eye irritant or a skin sensitizer.

b. Subchronic studies:

In a 6-month dog feeding study, the primary effects seen were congestion of the liver, hepatocyte swelling, increased liver weight, and an increase in colloidal vacuole in thyroid at 450 ppm. The No Observed Effect Level (NOEL) was 150 ppm. Levels tested were 0, 50, 150, and 450 ppm.

In a 90-day rat feeding study, the primary effects were hypertrophic change in the thyroid glands at 2,500 ppm. The NOEL was 500 ppm. Levels tested were 0, 250, 500 and 2,500 ppm.

In a 28-day mouse feeding study, diffuse and smooth granular livers and increased liver/body weight ratios were observed at 2,520 ppm. The NOEL was 420 ppm. Levels tested: 0, 70, 210, 420 and 2,520 ppm.

A 14-day inhalation study in the rat was submitted. Levels tested were 0.1, 1.0, and 10.0 milligrams (mg)/Liter (L). The NOEL was 10 mg/L.

A 21-day dermal toxicity study in the rabbit was performed on 80% WP (Wettable Powder) norflurazon. Levels tested were 750 mg/kilogram (kg)/day and 2000 mg/kg/day. The NOEL was greater than (>) 2000 mg/kg/day.

c. Chronic-feeding studies:

In a 2-year feeding study rats were fed dietary levels of 2, 15, 125, 375 and 1025 ppm of technical norflurazon. In the high dose group histopathological alterations included an increase in the number of chromophobe adenomas of the pituitary, nodular or cortical hypertrophy in adrenals and nephritis and/or casts in kidneys of the male rats; and fatty changes in adrenals, edometritis and squamous metaplasia of the uterus, cystic ovaries and hyaline casts and/or nephritis in kidneys of the females. A NOEL was demonstrated at 375 ppm. Norflurazon demonstrated no tumorigenic effect in the test animals in any of the dose levels tested.

In a 2-year feeding study, mice were fed 0, 85, 340 and 1360 ppm of technical norflurazon. Histopathological alterations included hepatoma/ hyperplasia - hypertrophy in the liver at 1360 ppm. The NOEL level observed was 340 ppm. There was no significant increase in these lesions in the lower levels over that of the control. The failure to induce such lesions in other long term studies permits the conclusion that this is not a potential carcinogenic response, but a toxic response to rather high level of chemical insult.

d. Reproduction studies:

A 3-generation reproduction study was conducted in the rat. Norflurazon was fed at dietary levels of 0, 125, 375 and 1025 ppm for three generations. At 1025 ppm norflurazon caused reduced fertility, gestation and viability indices. No teratogenic effects were seen at any dose tested. The NOEL was established at 375 ppm.

In a 1-generation reproduction study in the mouse, norflurazon was fed at dietary levels of 0, 0 85, 170 and 340 ppm. No adverse findings were observed in any of the doses tested. The NOEL was established at 340 ppm.

e. Teratogenicity studies:

Pregnant rabbits were fed a diet containing 0, 10, 30, and 60 mg/kg norflurazon on gestation days 6 through 15. Norflurazon was not teratogenic at 60 mg/kg/day. Maternal body weight was decreased at 60 mg/kg. Fetotoxic effects seen at 30 and 60 mg/kg/day were decreased weight and incomplete ossified variations. Maternal toxic NOEL was observed at 30 mg/kg/ day. Fetotoxic NOEL was observed at 10 mg/kg/day.

In the second teratology study, pregnant rats were fed 0, 100, 200 and 400 mg/kg/day of norflurazon on gestation days 6 through 15. Norflurazon was not embryotoxic or teratogenic. The NOEL was 400 mg/kg/day.

f. Mutagenicity studies:

In two Ames mutagenicity assays, norflurazon was tested in Samonella typhimurium strains, TA-1535, TA-1537, TA-1538, TA-98, TA-100 and D-4 Saccharomyces cerevisiae strain. The doses employed ranged from 0.1 micrograms (ug) to 500 ug per plate. The compound was tested directly in the presence of liver microsomal enzyme preparation from Aroclor induced rats. Norflurazon did not demonstrate mutagenic activity.

A reverse mutagenicity assay using Salmonella typhimurium strains TA-1535, TA-1537, TAS-1538, TA-98 and T-100, also E. coli, WP2 hcr strain (Tryptophanrequiring strain) was conducted. The doses employed were 5, 10, 50, 1,000 and 5,000 ug per plate. Norflurazon was negative in this test.

g. Metabolism studies:
(^3H, ^{14}C)- norflurazon was administed by gavage to 10 male Wistar strain rats at a dose of 10 mg per day for 15 days. Approximately 17 percent of the administed dose was excreted in the urine and about 57 percent in the feces. Small amounts of the parent compound was isolated from the urine (0.1%) and larger amounts from the feces (5.4%). Only traces of radioactivity were present in the tissues examined. Three major pathways seem to be operative in detoxification of norflurazon in the male rat: Desmethylation, yielding desmethyl metabolite of norflurazon; a hydroxylation process involving the replacement of chlorine on carbon-4 of the pyridazinon ring; and conjugation through sulfur introduced at carbon-4 of the pyridazinon ring.

h. Technical norflurazon is considered relatively non-toxic to avian test species (mallard duck and bobwhite quail). Technical norflurazon is moderately to slightly toxic to aquatic (freshwater and marine) vertebrate and invertebrate organisms.

This rationale also supports positions #2, #3, and #4.

2. None of the risk criteria set forth in Title 40 Code of Federal Regulations (CFR) §162.11 have been exceeded by norflurazon.

3. No unique precautionary statements, protective clothing requirements or reentry intervals are required.

4. No use, formulation, manufacturing process or geographical restrictions are required.

5. Although the Agency is unable to complete a tolerance reassessment because of certain toxicology and residue chemistry data gaps, the Agency concludes that no change in present tolerances is indicated at this time. (Refer to Section G. TOLERANCE REASSESSMENT).

Rationale: Additional data are required to describe the metabolism of norflurazon in plants and animals. The stability of norflurazon and its desmethyl metabolite residues under storage in one representative crop and one animal product is required. Additional residue studies are needed to support the tolerances for soybeans, citrus, apples, plums, hops and peanuts. Based on residue chemistry and toxicological considerations no evidence exists to suggest that the current tolerances are likely to expose the public to unreasonable adverse effects during the time necessary to conduct the studies required for a tolerance assessment.

6. The groundwater studies (hydrolysis, photodegradation, mobility, metabolism and dissipation) are being requested in an accelerated timeframe to assess the potential for norflurazon to contaminate groundwater.

   Rationale: Norflurazon residues appear to be relatively mobile in most mineral soils and immobile in soils with high organic matter. The half-life in soils ranges from 38 days to 731 days. The mobility and persistance of norflurazon presents a potential to contaminate groundwater. However, in monitoring studies conducted to date norflurazon has not been found in groundwater. Therefore, these studies are being requested on an expedited basis and will be evaluated as they are received and the Agency will determine then if the registration(s) of norflurazon will be affected.

7. Manufacturing-use pesticide products containing norflurazon as a sole active ingredient may be registered for sale, distribution and reformulation, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develope additional data, as specified in the tables, in order to maintain existing registrations or to permit new norflurazon registrations.

   Rationale: Under FIFRA, the Agency cannot cancel or withhold registration simply because data are missing or inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated when they are received and the Agency will determine at that time if they will affect the registration(s) of norflurazon.

D. Criteria for Registration Under This Standard

To be subject to this standard, manufacturing use products must meet the following conditions:

1. Contain norflurazon as the sole active ingredient and,

2. Conform to the acute toxicity limits, product composition, and use pattern requirements listed in Section E of this document.

The applicant for registration or reregistration of products subject to this standard must comply with all terms and conditions described in it, including commiting to fill data gaps on a schedule agreed to by both this Agency and the applicant. All applicants for registration under this standard must follow the instructions contained in this standard and complete and submit the appropriate forms within the time specified.

E. Acceptable Ranges and Limits

1. Product Composition Standard

To be covered under this Standard manufacturing-use products must contain norflurazon as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and manufacturing-use products containing norflurazon with a Toxicity Category IV for all acute studies.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing norflurazon may be labeled for formulation into end-use products for the commodities listed below. The attached index entry lists all registered uses, as well as approved maximum application rates and frequencies.

a. Terrestrial, non-domestic, food uses on: cranberries, cotton, soybeans, almonds, apples, apricots, cherries, citrus (all), filberts, hops, nectarines, peaches, pears, pecans, plums, prunes, and walnuts.

b. Terrestrial, non-domestic, non-food uses: noncrop areas such as storage areas, airports and rights-of-way.

F. Required Labeling

All manufacturing-use norflurazon products must bear appropriate labeling as specified in 40 CFR 162.10. The guidance package for this Standard contains information on label requirements.

In addition to the above, the following information must appear on the labeling:

1. The labeling must list specific, currently registered sites on which the product is intended for use after manufacture into an end-use-product or the manufacturing-use-product will be considered for manufacture into end-use-products for all registered use sites

2. The labeling must incorporate the following environmental precautionary statements that are specified in the proposed 40 CFR §156.55(c)(3) published in the Federal Register of Sept. 26, 1984:

> Do not discharge effluent containing this product directly into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying in writing the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency.

G. Tolerance Reassessment

U.S. tolerances for residues of norflurazon and its desmethyl metabolite in or on raw agriculural commodites are as follows [40 CFR §180.356(a)]:

Commodites	Maximum Residue Limit (ppm)
Almond, hulls	1.0
Almonds, meat	0.1
Apricots	0.1
Apples	0.1
Cattle, fat	0.1
Cattle, meat	0.1
Cattle, meat-by-prodcuts (mbyp)	0.1
Cherries	0.1
Citrus fruit	0.2
Cottonseed	0.1
Cranberries	0.1
Filberts	0.1
Goats, fat	0.1
Goats, meat	0.1
Goats, mbyp	0.1
Hogs, fat	0.1
Hogs, meat	0.1
Hogs, mbyp	0.1
Hops, green	1.0
Horses, fat	0.1
Horses, meat	0.1
Horses, mbyp	0.1
Milk	0.1
Nectarines	0.1
Pecans	0.1
Peaches	0.1
Pears	0.1
Plums (fresh prunes)	0.1
Poultry, fat	0.1
Poultry, meat	0.1
Poultry, mbyp	0.1
Sheep, fat	0.1
Sheep, meat	0.1
Sheep, mbyp	0.1

Soybeans	0.1
Soybean forage	1.0
Soybean hay	1.0
Walnuts	0.1

U.S. tolerances for indirect residues of norflurazon and its desmethyl metabolite in raw agriculural commodites when present as a result of application to cotton when peanuts are a replacement or follow-up crop are as follows [40 CFR §180.356(b)]:

Commodities	Maximum Residue Limit (ppm)
Peanuts	0.2
Peanut, hay	0.5
Peanut, hulls	0.5
Peanut, vines	0.5

A food additive tolerance has been estalished for residues of norflurazon and its desmethyl metabolite in dried hops at 3.0 ppm [21 CFR §193.324].

Feed additive tolerances have been established for residues of norflurazon and its desmethyl metabolite in citrus molasses at 1.0 ppm and dried citrus pulp at 0.4 ppm [21 CFR §561.283].

No Codex Almentarius or Mexican or Canadian tolerances have been established for residues of norflurazon on the above commodites.

The acceptable daily intake (ADI) was established using the 6-month dog feeding study with a no observed effect level (NOEL) of 150 ppm (3.75 mg/kg/day). Using a 1,000 fold safety factor, the ADI is calculated to be 0.0038 mg/kg/day. The maximum permitted intake (MPI) for a 60 kg human is calculated to be 0.225 mg/day. The current theoretical maximum residue contribution (TMRC) for norflurazon, based on the established tolerances, is 0.0877 mg/day for a 1.5 kg diet and the percent ADI utilized is 38.98%.

Residue studies are adequate to support tolerances established for almonds, apricots, cherries, cranberries, cottonseed, filberts, grapes, nectarines, peaches, peanuts hulls, pears, pecans, walnuts, milk, and the fat, meat, and meat by-products of cattle, goats, hogs, horses, poultry, and sheep.

NORFLURAZON*

h105801

TYPE PESTICIDE: Herbicide

FORMULATIONS:

Tech: 97%
G: 5%
WP: 80%
FlC: 5 lb/gal

GENERAL WARNINGS AND LIMITATIONS: A preplant incorporated or preemergent herbicide; it will not control emerged weeds.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Chlorosis.

MODE OF ACTION: Norflurazon is a plant pigment inhibitor.

LIVESTOCK TOLERANCES: 0.1 ppm in milk; 0.1 ppm in fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep.

REPLACEMENT CROP TOLERANCES: 0.2 ppm in peanuts, 0.5 ppm in peanut hay, hulls and vines as an indirect tolerance resulting from an application to cotton.

BROADLEAF WEEDS CONTROLLED:

annual bursage	(g)	PBFBMBA
bracted plantain	(h)	PDKABBA
buckhorn plantain	(h)	PDKABBC
Carolina geranium	(g)	PBZACBA
carpetweed	(d,i)	PADABBA
chickweed	(g,i,j)	PAZAAAC
cocklebur	(e,f)	PBFDQAA
common lambsquarters	(h,k)	PBDAEBA
common purslane	(g,i,j)	PEDADBA
cudweed	(g)	PBFBPAA
dogfennel	(g)	PBFBIBB
falsedandelion	(g,i,j)	PBFCUAA
fiddleneck	(g,i,j)	PARABAA
Florida pusley	(d,i)	PEMAEBB
geranium	(g)	PBZACAA
groundsel	(h,k)	PBFCXAA
hemp sesbania	(f)	PCQBSBB
henbit	(h)	PCOAFBA
horseweed	(h,i,j)	PBFAYBA
little mallow	(g,i,j)	PDAAHBD

*4-chloro-5-(methylamino)-2-(alpha,alpha,alpha-trifluoro-m-tolyl)-3(2H)-pyridazinone

BROADLEAF WEEDS CONTROLLED:
(continued)

london rocket	(g,i,j)	PBKBDBB
morningglory	(e,f)	PBGAAAB
Pennsylvania smartweed	(d,i)	PEAAGBO
pigweed	(d,i)	PAAAABI
pineappleweed	(g,i,j)	PBFCKBB
poorjoe	(h)	PEMACBA
prickly sida	(d,i)	PDAAJBF
prostrate spurge	(g)	PBVAGBQ
puncturevine	(g,i,j)	PFMAFBB
purslane	(d)	PAAAABP
ragweed	(f,i)	PBFAEAA
redmaids rockpurslane	(g,i,j)	PEDABBA
redroot	(b)	PCCABBA
redroot pigweed	(h,k)	PAFACBI
redstem filaree	(g,i,j)	PBZABBB
Russian thistle	(g,i,j)	PBDAKBA
shepherdspurse	(g,i,j)	PBKAHBA
sicklepod	(d,i)	PCQAMBF
silverleaf nightshade	(h)	PBWAFBR
smartweed	(f)	PEAAGAD
sowthistle	(g,i,k)	PBFDCAA
spotted spurge	(d)	PBVAGBK
spurge	(i)	PBVAGAA
spurred anoda	(d,i)	PDAACBA
tumble pigweed	(h,k)	PAFACBA
velvetleaf	(d)	PDAABBB
virginia pepperweed	(g)	PBKAWBG
whitestem filaree	(g,i,j)	PBZABBC
wild buckwheat	(g)	PEAAGBH

GRASSES AND OTHER MONOCOTS CONTROLLED:

alta fescue	(g)	PCABMBE
annual bluegrass	(g,i,j)	PCACKBA
annual sedge	(g)	PZAAAAI
bahiagrass	(g)	PCACFBM
barnyardgrass	(a,d,g,i,j)	PCABHBB
bermudagrass	(f,h,k)	PCAAZBA
bog rush	(b)	PCLABBL
broadleaf signalgrass	(g)	PCAARBD
broomsedge	(b)	PCAAHBH
cheat	(g)	PCAATBK
crabgrass	(d,g,i,j)	PCABFAA
cyperus dentatus	(b)	PBMADBP
downy brome	(g,i)	PCAATBM
fall panicum	(b,g)	PCACEBD
feather fingergrass	(g)	PCAAXBF
foxtail	(d)	PCACUAA

GRASSES AND OTHER MONOCOTS CONTROLLED:
(continued)

goosegrass	(d,i)	PCABIBA
green foxtail	(g,i)	PCACUBF
Italian ryegrass	(g,i,j)	PCABZBA
johnsongrass	(f,h)	PCACWBC
johnsongrass (seedling)	(d,i)	PCACWBG
little bluestem	(b)	PCAAHBF
needlegrass	(a)	PCADAAA
nutsedge	(f)	PBMADAA
orchardgrass	(h)	PCABBBA
panicum	(d,i)	PCACEAA
purple nutsedge	(h,k)	PBMADBM
quackgrass	(h,k)	PCAACBA
redtop	(b)	PCAADBA
rice cutgrass	(a)	PCABXBB
ripgut brome	(g,i,j)	PCAATBI
rough bentgrass	(b)	PCAADBE
signalgrass	(d)	PCAARAA
sixweeks grama	(g)	PCAAQBB
smokegrass	(a)	PCACBBE
southwestern cupgrass	(g,i)	PCABLBA
spikerush	(b)	PBMAEAA
stargrass	(c)	PCAAXAB
switchgrass	(c)	PCACEBM
Texas panicum	(g)	PCACEBL
wild barley	(g,i,j)	PCABSBD
wild onion	(g)	PCTABBB
wirestem muhly	(h)	PCACBBB
witchgrass	(g,i,j)	PCACEBC
woolgrass bulrush	(c)	PBMAGBE
yellow foxtail	(g,i)	PCACUBD
yellow nutsedge	(h)	PBMADBI

(a) control in cranberries at 4-6 lb a.i./A
(b) control in cranberries at 6-8 lb a.i./A
(c) control in cranberries at 8 lb a.i./A
(d) control in cotton and soybeans at 1-2 lb a.i./A
(e) control in cotton with split applications at 0.5-1.0 lb a.i./A
(f) suppression in cotton and soybeans at 1-2 lb a.i./A
(g) control in tree fruit, nut and citrus crops and in hops at 2-4 lb a.i./A
(h) suppression in tree fruit, nut and citrus crops and in hops at 2-4 lb a.i./A
(i) control in noncrop sites at 4-8 lb a.i./A
(j) control in tree fruit and nut crops at 1.88-3.75 lb a.i./A
(k) suppression in tree fruit and nut crops at 1.88-3.75 lb a.i./A

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Almond Cherry	0.1 ppm (almonds, cherries) 1.0 ppm (almond hulls) Make only one application per year. Do not apply when nuts or fruit are on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Do not use in deciduous crops in the following locations: Arizona, and the Coachella, Imperial, Palo Verde and Tehachapi Valleys of California. Do not use in stone fruits on the western slope of Colorado. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or soils having organic matter content of greater than 3%. Reduce dosage in proportion to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	03001AA 05002AA
3-4 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge; avoid contact with fruit or foliage. In CA and the Pacific Northwest apply from October through the end of January. Elsewhere apply from fall to early spring before weeds emerge. Use only on trees that have been established at least 18 months in the field. Do not use on coarse textured soils. May be tank mixed with paraquat dichloride in 200 gallons of water per acre.	
2-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Do not use on coarse soils. Tank mix with simazine.	
1.4-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Do not use on sand, loamy sand, gravelly soils or exposed subsoils, or in soils with less than 1% organic matter. Do not use in AZ or CA. Tank mix with diuron.	
	Refer to Cherry for additional information pertinent to only that site.	

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Apple Peach	0.1 ppm Make only one application per year. Do not apply when fruit is on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Do not use in deciduous crops in the following locations: Arizona, and the Coachella, Imperial, Palo Verde and Tehachapi Valleys of California. Do not use in stone fruits on the western slope of Colorado. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or soils having organic matter content of greater than 3%. Reduce dosage in proporation to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	04001AA 05004AA
2-4 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Application may be made to newly planted trees, provided the soil around the tree is firm and there are no depressions in which rain or irrigation water could accumulate. In CA and the Pacific Northwest, peach trees must be established at least 18 months in the field. May be tank mixed with paraquat dichloride in 200 gallons of water per acre.	
2-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Do not use on coarse soils. Tank mix with simazine.	
1.4-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Do not use on sand, loamy sand, gravelly soils or exposed subsoils, or in soils with less than 1% organic matter. Do not use in AZ or CA. Tank mix with diuron.	
	Refer to Peach for additional information pertinent to only that site.	

NORFLURAZON

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Apricot Filbert Nectarine Pear Plum Prune Walnut	0.1 ppm Make only one application per year. Do not apply when nuts or fruit are on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Do not use in deciduous crops in the following locations: Arizona, and the Coachella, Imperial, Palo Verde and Tehachapi Valleys of California. Do not use in stone fruits on the western slope of Colorado. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or soils having organic matter content of greater than 3%. Reduce dosage in proporation to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	05001AA 03005AA 05003AA 04003AA 05005AA 05006AA 03009AA
2-4 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. In CA and the Pacific Northwest, trees must be established at least 18 months in the field. Elsewhere, trees must be established at least 12 months in the field. May be tank mixed with paraquat dichloride in 200 gallons of water per acre.	
2-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage, or stems. Do not use on coarse soils. Tank mix with simazine.	
1.4-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Do not use on sand, loamy sand, gravelly soils or exposed subsoils, or in soils with less than 1% organic matter. Do not use in AZ or CA. Tank mix with diuron.	

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Apricot cluster (continued)		
1.88-3.75 (5 lb/gal FlC)	Use limited to CA and West of the Cascade Mountains in OR and WA. Directed spray. Broadcast or band. Apply from fall to early spring in CA. In OR and WA, apply before weed growth resumes in the spring. Do not use on pear trees.	
Cherry	0.1 ppm Make only one application per year. Do not apply when fruit is on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Do not use in deciduous crops in the following locations: Arizona, and the Coachella, Imperial, Palo Verde and Tehachapi Valleys of California. Do not use on the western slope of Colorado. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or soils having organic matter content of greater than 3%. Reduce dosage in proportion to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	05002AA
1.88-3.75 (5 lb/gal FlC)	Use limited to CA and West of the Cascade Mountains in OR and WA. Directed spray. Broadcast or band. Apply from fall to early spring in CA. In OR and WA, apply before weed growth resumes in the spring. Refer to the Almond cluster for additional information.	

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Citrus Fruits	0.2 ppm (citrus fruit) 0.4 ppm (dried citrus pulp) 1.0 ppm (citrus molasses) Make only one application per year. Do not apply when fruit is on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Do not use in deciduous crops in the following locations: Arizona, and the Coachella, Imperial, Palo Verde and Tehachapi Valleys of California. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or soils having organic matter content of greater than 3%. Reduce dosage in proportion to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	02000AA
2-4 (80% WP)	Directed spray. Broadcast or band. Apply any time during the year, according to local practice. The higher rates can also be used in coarse textured soils and incorporated to a depth of not more than 3-4 inches for increased activity against less susceptible weeds. Do not use where citrus is interplanted with palm trees. It may be applied in newly planted citrus. May be tank mixed wth paraquat dichloride in 200 gallons of water per acre.	
2-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Do not use on coarse soils. Tank mix with simazine.	
1.4-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage and stems. Do not use on sand, loamy sand, gravelly soils or exposed subsoils, or in soils with less than 15% organic matter. Tank mix with diuron	

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Cotton	0.1 ppm (cottonseed) Do not graze treated fields with livestock or feed treated cotton forage to livestock. Cover crops planted after harvest should be plowed under and not grazed. To minimize injury to small grain cover crops, they should be broadcast planted rather than drilled. For one year following application, treated acreage may only be rotated to cotton, soybeans, and peanuts. General information: Use limited to AL, AR, North FL, GA, IL, KY, LA, MI, MO, NC, SC, TN, TX and VA. If replanting is necessary, a light reworking of the topsoil will retain the herbicidal activity. Peanuts can be planted as a replacement crop 30 days after application. The quantity of the chemical applied in any one year must not exceed the broadcast rate in pounds per acre for a given soil type. Make applications in 5 or more gallons of water per acre with a drift control agent by air. Apply in 10-20 gallons of water per acre with ground equipment. In areas with less than 40 inches of rainfall, apply as a preplant incorporated or split application only. Reduce dosage in proportion to band area actually treated. May be tank mixed with those DNA-type herbicides registered for use in cotton.	28007AA
1-2 (80% WP)	Preplant incorporated. Broadcast or band. Apply from 30 days to just prior to planting and incorporate not deeper than 2-3 inches within one week after application.	
1-2 (80% WP)	Preemergence. Broadcast or band. Apply at the time of planting and before weed emergence.	
0.5-1.0 (80% WP)	Split application. Broadcast or band. Apply preplant from 30 days to just prior to planting, and incorporate not deeper than 2-3 inches within one week after application. Make a second application at planting time as a preemergent surface spray at the same dosage rate.	

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTRUAL CROPS		
Cranberry	0.1 ppm Make only one application per year.	01010AA
4-8 (5% G)	Use limited to MA, NJ, OR, WA, and WI. Broadcast. Make a single application in the early spring after removal of winter flood and before weed growth resumes, or in the fall after harvest at least 2 weeks before winter flood. Apply uniformly by ground or air. In the spring, flooding after application may reduce weed control. Do not exceed 4 lb a.i./A/year in a newly planted bog.	
Filbert	See Apricot cluster.	
Hops	3.0 ppm (dried hops) 1.0 ppm (green hops) Make only one application per year. Do not apply when fruit is on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or soils having organic matter content of greater than 3%. Reduce dosage in proportion to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	08020AA
2-4 (80% WP)	Directed spray. Broadcast or band. Apply in the fall after the hop yards have been worked for the last time, or within one week after stringing in the spring. Use only on hops that have been established at least 18 months in the field.	
Nectarine	See Apricot cluster.	

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Peach	0.1 ppm Make only one application per year. Do not apply when fruit is on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Do not use in deciduous crops in the following locations: Arizona, and the Coachella, Imperial, Palo Verde and Tehachapi Valleys of California. Do not use on the western slope of Colorado. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or soils having organic matter content of greater than 3%. Reduce dosage in proportion to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	05004AA
1.88-3.75 (5 lb/gal FlC)	Use limited to CA and west of the Cascade Mountains in OR and WA. Directed spray. Broadcast or band. Apply from fall to early spring in CA. In OR and WA, apply before weed growth resumes in the spring.	
	Refer to Apple cluster for additional information.	
Pear	See Apricot cluster.	
Pecan	0.1 ppm Make only one application per year. Do not apply when nuts are on the ground at harvest. Do not graze livestock on treated areas. Do not feed or graze cover crops grown in treated orchards. General information: The chemical must be moved into the root zone to be effective. If no rainfall occurs within four weeks after application, the product must be activated by flood or sprinkler irrigation. Do not use in deciduous crops in the following locations: Arizona, and the Coachella, Imperial, Palo Verde and Tehachapi Valleys of California. Use the lower rates on coarse soils. Use the higher rates on medium to fine soils or	03008AA

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Pecan (continued)		
	soils having organic matter content of greater than 3%. Reduce dosage in proportion to band area actually treated. Do not use on nursery stock. Apply in 20-100 gallons of water per acre.	
2-4 (80% WP)	Directed spray. Broadcast or band. Apply from fall to early spring before weeds emerge, avoiding contact with fruit, foliage or stems. Application may be made to newly planted trees in the Southeast. Elsewhere, trees must be established at least 12 months in the field. Do not use on nonbearing trees in AZ and NM. May be tank mixed with paraquat dichloride in 200 gallons of water per acre.	
2-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage or stems. Do not use on coarse soils. Tank mix with simazine.	
1.4-3 (80% WP)	Directed spray. Broadcast or band. Apply before weeds emerge, avoiding contact with fruit, foliage and stems. Do not use on sand, loamy sand, gravelly soils or exposed subsoils, or in soils with less than 1% organic matter. Do not use in AZ or CA. Tank mix with diuron.	
Plum	See Apricot cluster.	
Prune	See Apricot cluster.	
Soybeans	0.1 ppm (soybeans) 1.0 ppm (forage and hay) Cover crops planted after harvest should be plowed under and not grazed. To minimize injury to small grain cover crops, they should be broadcast planted rather than drilled. For one year following application, treated acreage may only be rotated to cotton, soybeans and peanuts. General information: Use limited to AL, AR, North FL, GA, IL, KY, LA, MI, MO, NC, SC, TN, TX, and VA. If replanting is necessary, a light reworking of the topsoil will retain the herbicidal activity. The quantity of the chemical applied in any one year	28023AA

NORFLURAZON

Site, Dosage and Formulations (lb a.i./A)	Tolerance, Use, Limitations	
AGRICULTURAL CROPS		
Soybeans (continued)		
	must not exceed the broadcast rate in pounds per acre for a given soil type. Make applications in 5 or more gallons of water per acre with a drift control agent by air. Apply in 10-20 gallons of water per acre with ground equipment. In areas with less than 40 inches of rainfall, apply as a split application only. Reduce dosage in preportion to band area actually treated. May be tank mixed with those DNA-type herbicides registered for use in cotton; or with 4-amino-6-(1,1-dimethylethyl)-3-(methylthio)-1,2,4-triazin-5(4H)-one.	
1-2 (80% WP)	Preemergence. Broadcast or band. Apply at the time of planting and before weed emergence.	
0.5-1.0 (80% WP)	Split application. Broadcast or band. Apply preplant from 30 days to just prior to planting, and incorporate not deeper than 2-3 inches within one week after application. Make a second application at planting time as a preemergent surface spray at the same dosage rate.	
Walnut	See Apricot cluster.	
AGRICULTURAL PREMISES		
Uncultivated Agricultural Areas	General Information: Uncultivated agricultural areas include around buildings, storage areas, fencerows, etc.	66000OA
4-8 (80% WP)	General weed control. Apply in 20-100 gallons of water per acre before weeds emerge. Moisture is required within 2 weeks after application. Make only one application per year. Use the lower rate on coarse soils. Use the higher rates on medium to fine textured soils or on soils with higher than 3% organic matter content.	

Site, Dosage and Formulations	Tolerance, Use, Limitations	
RIGHTS-OF-WAY		
Rights-of-way	General Information: Rights-of-way include roadways, guard rails, highway medians, piplines, railroads, etc. Refer to Uncultivated Agricultural Areas under AGRICULTURAL PREMISES for use information.	67013OA
COMMERCIAL AND INDUSTRIAL PREMISES		
Noncrop Areas	General Information: Noncrop areas include around buildings, storage areas, fencerows, pumps, machinery, roadways, airports, military installations, lumberyards, industrial sites, etc. Refer to Uncultivated Agricultural Areas under AGRICULTURAL PREMISES for use information.	67000OA
AERIAL AND TANK MIX APPLICATIONS		
Aerial Applications		90015OA
—	Refer to AGRICULTURAL CROPS Cotton, Cranberry, Soybeans	
Tank Mix		99003OA
—	Refer to AGRICULTURAL CROPS Almond, Apple, Apricot, Cherry, Citrus fruits, Cotton, Filbert, Nectarine, Peach, Pear, Pecan, Plum, Prune, Soybeans, Walnut	

NORFLURAZON

Listing of Registered Pesticide Products by Formulation

97% technical chemical
  norflurazon (105801)
    011273-00010

5% granular
  norflurazon (105801)
    011273-00012

80% wettable powder
  norflurazon (105801)
    011273-00013   011273-00019   011273-00024

5 lb/gal flowable concentrate
  norflurazon (105801)
    011273-00032

EPA Index to Pesticide Chemicals

NORFLURAZON

Appendix B

Listing of Registration Numbers by Site

AGRICULTURAL CROPS

Almond	011273-00019		03001AA
Apple	011273-00019		04001AA
Apricot	011273-00019	011273-00032	05001AA
Cherry	011273-00019	011273-00032	05002AA
Citrus Fruits	011273-00019		02000AA
Cotton	011273-00013		28007AA
Cranberry	011273-00012		01010AA
Filbert	011273-00019	011273-00032	03005AA
Hops	011273-00019		08020AA
Nectarine	011273-00019	011273-00032	05003AA
Peach	011273-00019	011273-00032	05004AA
Pear	011273-00019	011273-00032	04003AA
Pecan	011273-00019		03008AA
Plum	011273-00019	011273-00032	05005AA

Listing of Registration Numbers by Site (continued)

Site	Registration Numbers	Code
Prune	011273-00019 011273-00032	05006AA
Soybeans	011273-00013	28023AA
Walnut	011273-00019 011273-00032	03009AA

AGRICULTURAL PREMISES

Site	Registration Numbers	Code
Uncultivated Agricultural Areas	011273-00024	66000OA

RIGHTS-OF-WAY

Site	Registration Numbers	Code
Rights-of-way	011273-00024	67013OA

COMMERCIAL AND INDUSTRIAL PREMISES

Site	Registration Numbers	Code
Noncrop Areas	011273-00024	67000OA

II. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA sec. 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-2) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA sec. 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data[1/] Must be Submitted. You may determine which generic data you must submit by consulting Table A at the end of this chapter. That table lists the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required studies must be conducted in accordance with EPA approved protocols (such as those contained in the Pesticide Assessment Guidelines [2/] or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical

---

[1/] Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

[2/] The Pesticide Assessment Guidelines are available in hard copy or microfiche from the National Technical Information Service, 5285 Port Royal Road, Springfield, Va. 22161.

formulation," and in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter III of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-3] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

(b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Pesticide Assessment Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

OR

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-4)*/

OR

---

*/ FIFRA sec. 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

(Footnote continued on next page)

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

OR

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

(Footnote continued from previous page)
In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON 1/

Data Requirement	Composition[2]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/
§158.120 Product Chemistry				
Product Identity and Composition				
61-1 - Product Identity and Disclosure of Ingredients	TGAI	Yes	00111653 00079434 GS-0229-1 GS-0229-2 GS-0229-3	No
61-2 Description of Beginning Materials and Manufacturing Process	TGAI	Partially	00111653 00079434 GS-0229-1 GS-0229-2 GS-0229-3	Yes
61-3- Discussion of Formation of Impurities	TGAI	No		Yes
Analysis and Certification of Product Ingredients				
62-1 - Preliminary Analysis of Product Samples	TGAI	No		Yes
Physical and Chemical Characteristics				
63-2 - Color	TGAI	Yes	00079434 00111653	No
63-3 - Physical State	TGAI	Yes	00079434 00111653	No
63-4 - Odor	TGAI	Yes	00079434 00111653	No

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]
§158.120 Product Chemistry (continued)				
63-5 - Melting Point	TGAI	Yes	00079434 00111653	No
63-6 - Boiling Point	N/A[5]	N/A		No[4]
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes
63-8 - Solubility	TGAI or PAI	Yes	00079434 00111653	No
63-9 - Vapor Pressure	PAI	Yes	00079434 00111653	No
63-10 - Dissociation constant	PAI	No		Yes
63-11 - Octanol/water partition coefficient	PAI	No		Yes
63-12 - pH	TGAI	No		Yes
63-13 - Stability	TGAI	Partially	00079434 00111653	Yes
Other Requirements:				
64-1 - Submittal of samples	N/A	N/A		No

[1] The 97% technical (TGAI) also serves as a manufacturing-use product, EPA Reg. No. 11273-10.
[2] Compostion: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient.
[3] Data must be submitted no later than six months after receipt of this guidance package.
[4] Not required because 97% technical is a solid at room temperature.
[5] N/A = Not applicable. Data requirement is not necessary for purposes of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.125 Residue Chemistry				
171-4 - Nature of Residue (Metabolism)				
- Plants	PAIRA	Partially	00047764 00092285 00111625 00104774 00037055 00047763 00095845	Yes[3]/
- Livestock	PAIRA and plant metabolites	Partially	00111607 00047765 00025638	Yes[4]/
171-4 - Residue Analytical Method (Plant and Animal residues)	TGAI and metabolites	Partially	00111648 00092296 00111667 00111669 00031642 00092294 00027375 00111625 00106025 00111651 00085081	Yes[5]/
171-4 - Storage Stability Data	PAI and metabolites	Partially	00111625	Yes[6]/

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.125 Residue Chemistry (continued)				
171-4 - Magnitude of the Residue (Residue studies for each food use)				
- Crop Group #1 - Legume Vegetables Group				
° Crop - Soybeans				
— Crop field trials	TEP	Partially	00111625	Yes[7a]/
-- Processed Food/Feed	EP	Partially	00111651 00031634 00079435 00111667	Yes[7b]/
- Crop Group #2 - Citrus Fruits Group				
° Crop - All Citrus Fruits				
— Crop field trials	TEP	Partially	00131027	Yes[8a]/
— Processed Food/Feed	EP	Partially	00106025	Yes[8b]/
- Crop Group #3 - Pome Fruits Group				
° Crop #1 - Apples				
— Crop field trials	TEP	Yes	00111648	No
— Processed Food/Feed	EP	Partially	00106025	Yes[9]/
° Crop #2 - Pears				
— Crop field trials	TEP	Yes	00111648	No

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.125 Residue Chemistry (continued)				
- Crop Group #4 - Stone Fruits Group				
• Crop #1 - Apricots				
— Crop field trials	TEP	Yes	00111655 GS-0299-4	No
• Crop #2 - Cherries				
— Crop field trials	TEP	Yes	00111641	No
• Crop #3 - Nectarines				
— Crop field trials	TEP	Yes	00111641 GS-0299-4	No
• Crop #4 - Peaches				
— Crop field trials	TEP	Yes	00111641 GS-0299-4 00106025	No
• Crop #5 - Plums (fresh prunes)				
— Crop field trials	TEP	Yes	00111641	No
— Processed Food/Feed	EP	Partially	GS-0299-4	Yes[10]/
- Crop Group #5 - Small Fruits and Berries Group				
• Crop #1 - Cranberries				
— Crop field trials	TEP	Yes	00037052 00111625	No

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.125 Residue Chemistry (continued)				
• Crop #2 - Grapes				
— Crop field trials	TEP	Yes	00111645	No
— Processed Food/Feed	EP	Yes	00128129 GS-0299-4	No
- Crop Group #6 - Tree Nuts Group				
• Crop #1 - Almonds				
— Crop field trials	TEP	Yes	00111648	No
• Crop #2 - Filberts				
— Crop field trials	TEP	Yes	00111641 00106025	No
• Crop #3 - Pecans				
— Crop field trials	TEP	Yes	00106036	No
• Crop #4 - Walnuts				
— Crop field trials	TEP	Yes	00111641	No
- Miscellaneous Commodities				
• Crop #1 - Cottonseed				
— Crop field trials	TEP	Yes	00092300	No
— Processed Food/Feed	EP	Yes	00092299 00111625	No

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.125 Residue Chemistry (continued)				
• Crop #2 - Hops				
— Crop field trials	TEP	Partially	00111648	Yes[11a,c]/
— Processed Food/Feed	EP	Partially	"	Yes[11b,c]/
• Crop #3 - Peanuts				
— Crop field trials	TEP	Partially	00111651	Yes[12a]/
— Processed Food/Feed	EP	Partially	"	Yes[12b]/
- Meat, Milk, Poultry and Eggs	TGAI or plant metabolites	Yes	00111648 00111669	No[13]/

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient radiolabeled; TEP= Typical end use product; EP = End use product

2/ Data must be submitted no later than 2 years after receipt of this guidance package.

3/ Additional Data Required: Data reflecting uptake, distribution, and metabolism of pyridazinone ring-labeled $[C^{14}]$ norflurazon in mature soybean, cotton, and one tree fruit. If metabolism data differ signficantly between these three crops, then metabolism data must be submitted for a representative crop in each registered crop grouping.

4/ Additional Data Required: Studies which elucidate the metabolism of norflurazon and its predominant plant residues in poultry (including eggs) and ruminants. If any additional major metabolites are determined in the repeated plant metabolism studies, they should be included in the diet. If the metabolism of norflurazon and its metabolites in poultry or ruminants is found to differ significantly from that in rats, a non-ruminant (swine) study will also be required.

5/ Additional Data Required: Extraction efficiency and residue data to determine if conjugated metabolites are of residue concern.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

§158.125 Residue Chemistry
(continued)

6/ Additional Data Required: Data demonstrating the stability of norflurazon and its desmethyl metabolite in or on representative crops (such as soybean seeds and forage/hay, cherries, apples, and a nut crop) and animal products (milk and tissue). One crop and one animal product would suffice. Spiked and weathered samples should be stored at subfreezing temperatures for intervals approximating those used to determine the magnitude of the residue.

7/ Additional Data Required: (a) Data reflecting residues in or on soybean forage, hay and straw following a preemergence application of a 80% WP formulation at registered application rates. If the data indicate tolerance exceeding residues at short treatment-to-sampling intervals, appropriate PHIs should be proposed. A tolerance for straw or a label restriction prohibiting its use as a feed item must be proposed. Tests should be conducted in AR, GA, IL and MO. (b) Data reflecting residues in meal, hulls, soapstock, and crude and refined oil processed from seed bearing measurable weathered residues. If residues are found to concentrate in any of these processed products appropriate food/feed additive tolerances must be proposed.

8/ Additional Data Required: (a) Data reflecting residues in or on whole FL-grown oranges, lemons, and grapefruit following a single directed-spray application of a 80% WP formulation at 8 lb ai/A. Samples must be taken within 1 day of treatment and at weekly intervals for one month. Alternatively, a 12-week PHI may be proposed for application in FL at greater than 4 lb ai/A. (b) Data reflecting residues in dried pulp, peel, oil, molasses and juice processed from oranges bearing measurable weathered residues. Should the concentration of residues in dried pulp and molasses differ from the established tolerances, appropriate changes in the tolerance should be proposed. If the data indicate that residues concentrate in peel, oil, or juice, appropriate food additive tolerances must be proposed.

9/ Additional Data Required: Data reflecting residues in dehydrated apple pomace processed from apples bearing measurable weathered residues. If residues are found to concentrate in dehydrated apple pomace, appropriate feed additive tolerances must be proposed.

10/ Additional Data Required: Residue data from dried prunes (plums) processed from fresh fruit bearing measurable weathered residues.

11/ Additional Data Required: (a) Residue data on fresh hops from application of a single directed spray treatment of a 80% WP formulation applied at registered rates. Tests must be conducted in WA. (b) Data reflecting residues in or on dried and spent hops processed from fresh hops bearing measurable weathered residues. If residues are found to concentrate in spent hops, an appropriate feed additive tolerance must be proposed. If concentration in dried hops varies from the established food additive tolerance, appropriate revision in the tolerance must be proposed (c) Alternatively to (a) and (b), data detailing the time and method of application, time of sampling, and storage time and conditions for the previously submitted residue trials.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

§158.125 Residue Chemistry
(continued)

12/ Additional Data Required: (a) Data reflecting residues of norflurazon and its desmethyl metabolite in or on peanut vines and hay grown from seed planted 30 days after a broadcast application of a 80% WP formulation at registered application rates. Tests must be conducted in GA, NC and TX. Alternatively a 10-week feeding and grazing restriction for peanut hay and vines can be proposed. (b) Data reflecting residues of norflurazon and its desmethyl metabolite in meal, crude oil, soapstock and refined oil processed from peanut nutmeat, bearing measurable weathered residues. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.

13/ Note: The metabolism of norflurazon is not adequately understood. Should new metabolites of concern be found, additional data will be required.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.130 Environmental Fate					
DEGRADATION STUDIES-LAB: [12]					
161-1 - Hydrolysis	TGAI or PAIRA	A,B	No		Yes[3]
Photodegradation					
161-2 - In water	TGAI or PAIRA	A,B	No		Yes[3]
161-3 - On soil	TGAI or PAIRA	A,B	No		Yes[3]
161-4 - In Air	N/A[13]	N/A	N/A		No[5]
METABOLISM STUDIES-LAB: [12]					
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No		Yes[4]
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes[4][6]
162-3 - Anaerobic Aquatic	TGAI or PAIRA	A[7]	No		Yes[4]
162-4 - Aerobic Aquatic	TGAI or PAIRA	A[7]	No		Yes[4]
MOBILITY STUDIES: [12]					
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	No		Yes[3]
163-2 - Volatility (Lab)	N/A	N/A	N/A		No[5]
163-3 - Volatility (Field)	N/A	N/A	N/A		No[5]

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]	Use[2] Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.130 Environmental Fate (continued)					
DISSIPATION STUDIES-FIELD:					
164-1 - Soil	TEP	A,B	No		Yes[4]
164-2 - Aquatic (Sediment)	TEP	A[7]	No		Yes[4]
164-3 - Forestry	N/A	N/A	N/A		No
164-4 - Combination and Tank Mixes	N/A	N/A	N/A		No
164-5 - Soil, Long-term	TEP	A	No		Yes[8]
ACCUMULATION STUDIES:					
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[4]
165-2 - Rotational Crops (Field)	TEP	A	N/A		No[9]
165-3 - Irrigated Crops	N/A	N/A	N/A		No[10]
165-4 - In Fish	TGAI or PAIRA	A,B	N/A		No[11]
165-5 - In Aquatic Non-Target Organisms	N/A	N/A	N/A		No

---

[1] Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food.

[3] Data must be submitted no later than 6 months after receipt of this guidance package.

[4] Data must be submitted no later than 2 years after receipt of this guidance package.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

§158.130 Environmental Fate
(continued)

5/ Not required because norflurazon has a low vapor pressure.

6/ Data from an anaerobic soil study need not be submitted if an anaerobic aquatic study is submitted.

7/ Due to the persistence and likelihood of residues in the aquatic environment this study is required for use on cranberries.

8/ Data must be submitted no later than 4 years after receipt of this guidance package.

9/ Depending on results of #165-1, confined rotational crop study, these data may be required.

10/ Not required because water irrigating cranberries is not used on other crops.

11/ Depending on the octanol/water partition coefficient, these data may be required.

12/ Note: Do lab tests first to ascertain the complete degradative pathway. Identification of norflurazon and desmethyl norflurazon is inadequate for all tests that require metabolite identification.

13/ N/A = Not applicable. Data requirement is not necessary for purposes of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Use[2]/ Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)
§158.135 Toxicology					
ACUTE TESTING:					
81-1 - Oral - Rat	TGAI	A,B	Yes	00111612	No
81-2 - Dermal - Rabbit	TGAI	A,B	Yes	00111612	No
81-3 - Inhalation - Rat	TGAI	A,B	Yes	00112980 00111614	No
81-7 - Delayed Neurotoxicity - Hen	N/A[5]/	N/A	N/A		No
SUBCHRONIC TESTING:					
82-1 - 90-Day Feeding - Rodent, Non-rodent	TGAI	A,B	Yes	00091055 00111618	No
		A,B	Yes	00092290	No
82-2 - 21-Day Dermal - Rabbit	TGAI	N/A	N/A		No
82-3 - 90-Day Dermal - Rabbit	N/A	N/A	N/A		No
82-4 - 90-Day Inhalation - Rat	N/A	N/A	N/A		No
82-5 - 90-Day Neurotoxicity-Hen/Mammal	N/A				
CHRONIC TESTING:					
83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent	TGAI	A	Yes	00082019 00041015 00041016 00111649	No

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]	Use[2] Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.135 Toxicology (continued)					
83-2 - Oncogenicity - 2 species: Rat and Mouse preferred	TGAI	A	Yes	00082019 00041015 00041016 00111649	No
83-3 - Teratogenicity - 2 species	TGAI	A,B	Yes	00063621 00131151 00131152	No
83-4 - Reproduction - Rat 2-generation	TGAI	A	Yes	00080750 00080751	No
MUTAGENICITY TESTING					
84-2 - Gene Mutation	TGAI	A,B	Yes	00072974	No
84-2 - Chromosomal Aberration	TGAI	A,B	No		Yes[3]
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	No		Yes[3]
SPECIAL TESTING					
85-1 - General Metabolism	PAI or PAIRA	A	Partially	00047765	Yes[4]
85-2 - Domestic Animal Safety	N/A	N/A	N/A		No

---

[1] Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; PAIRA = Pure active ingredient, radiolabelled.

[2] The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food.

[3] Data must be submitted no later than 1 year after receipt of this guidance package.

[4] Requires a female rat metabolism study. Data must be submitted no later than 6 months after receipt of this guidance package.

[5] N/A = Not applicable. Data requirement is not necessary for purposes of this standard.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	N/A	N/A	N/A		No1/
132-1 - Soil Dissipation	N/A	N/A	N/A		No1/
133-1 - Dermal Exposure	N/A	N/A	N/A		No1/
133-4 - Inhalation Exposure	N/A	N/A	N/A		No1/

1/ Not Applicable. Data to support establishment of reentry protection standards are not required because the Agency has determined, based on use patterns and toxicology data for norflurazon, that the criteria in part 158.140 are not met.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Use[2]/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/
§158.145 Wildlife and Aquatic Organisms					
AVIAN AND MAMMALIAN TESTING					
71-1 - Avian Oral	TGAI	A,B	Yes	00048362** 00063622*	No
71-2 - Avian Dietary - Bobwhite quail Mallard duck	TGAI	A,B	Yes	00037051** 00077292**	No
71-3 - Wild Mammal Toxicity	N/A[11]/	N/A	N/A		No
71-4 - Avian Reproduction - Mallard duck Bobwhite quail	TGAI	A,B	Partially	00052172* 00039222*	[Reserved][4]/
71-5 - Simulated and Actual Field Testing - Mammals and Birds	N/A	N/A	N/A		No
AQUATIC ORGANISM TESTING					
72-1 - Freshwater Fish - Bluegill sunfish Rainbow trout	TGAI	A,B	Yes	00087862** 00087863**	No
72-2 - Acute Freshwater Invertebrates	TGAI	A,B	Yes	00035709**	No
72-3 - Acute Estuarine and Marine Organisms	TGAI	A,B	Partially	00045704*	No[5]/

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition[1]/	Use[2]/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/
§158.145 (continued)					
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle - Daphnia magna Fathead minnow Rainbow trout	TGAI	A,B	Yes	00118049** 00118047** 00118048**	No
72-5 - Fish - Life-Cycle	N/A	N/A	N/A		No
72-6 - Aquatic Organism Accumulation	N/A	N/A	N/A		No
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	No		No[6]/
§158.155 Nontarget Insect					
NONTARGET INSECT TESTING - POLLINATORS:					
141-1 - Honeybee acute contact	TGAI	A,B	No		Yes
141-2 - Honeybee - toxicity of residues on foliage	TEP	A,B	No		No[7]/
141-4 - Honeybee subacute feeding study	[Reserved][8]/				
141-5 - Field testing for pollinators	TEP	A,B	No		No[9]/

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Data Requirement	Composition1/	Use2/ Pattern	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?3/
NONTARGET INSECT TESTING - AQUATIC INSECTS:					
142-1 - Acute toxicity to aquatic insects	[Reserved]10/				
142-2 - Aquatic insect life-cycle study	[Reserved]10/				
142-3 - Simulated or actual field testing for aquatic insects	[Reserved]10/				
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	[Reserved]10/				

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product; PAI = pure active ingredient.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food.

3/ Data must be submitted no later than 6 months after receipt of this guidance package.

4/ These studies may be required if the Environmental Fate Data indicates that the Estimated Environmental Concentration (E.E.C.) exceeds the maximum dose level, 40 ppm, of the currently acceptable reproduction studies.

5/ The 96-hour studies for shrimp and an estuarine or marine fish may be required if the Environmental Fate Data indicates that significant concentrations of norflurazon are expected to enter the estuarine or marine enviroment.

TABLE A
GENERIC DATA REQUIREMENTS FOR NORFLURAZON

Wildlife and
Aquatic Organisms
(continued)

6/ This study may be required if the Environmental Fate Data indicates that norflurazon residues exceed the acute or chronic toxicity levels and are persistant to the extent that population impact must be determined.

7/ This study may be required, depending on results of the acute contact toxicity study.

8/ Reserved pending development of test methodology.

9/ Requirement for field testing is dependent on results of lower tier studies.

10/ Reserved pending Agency decision as to whether the data requirement should be established.

11/ N/A = Not Applicable. Data requirement is not necessary for purposes of this standard.

* Fulfills data requirement in combination with other studies.

** Fulfills data requirement on its own.

III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: Unless stated otherwise in Section I, Regulatory Position and Rationale, this Section applies only to manufacturing use products, not to end use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA sec. 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data By Submitted Under §3(c)(2)(B)."

---

*/ Product specific data pertain to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicity data.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NORFLURAZON, EPA Reg. No. 11273-10 (97% Technical)

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.120 Product Chemistry				
Product Identity and Composition:				
61-1 - Identity of Ingredients	MP	Yes	00111653 00079434 GS-0229-1 GS-0299-2 GS-0229-3	No
61-2 - Description of Beginning Materials and Manufacturing Process	MP	Partially	00111653 00079434 GS-0229-1 GS-0229-2 GS-0229-3	Yes
61-3 - Discussion of Formation of Impurities	MP	No		Yes
Analysis and Certification of Product Ingredients:				
62-1 - Preliminary Analysis of Product Samples	MP	No		Yes
62-2 - Certification of Limits	MP	Partially	00111653 00079434 GS-0229-1 GS-0229-2 GS-0229-3	Yes

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NORFLURAZON,
EPA Reg. No. 11273-10 (97% Technical)

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.120 Product Chemistry (continued)				
62-3 - Analytical Methods for Enforcement of Limits	MP	Partially	00111653 00079434 GS-0229-1 GS-0229-2 GS-0229-3	Yes
Physical and Chemical Characteristics				
63-2 - Color	MP	Yes	00079434 00111653	No
63-3 - Physical State	MP	Yes	00079434 00111653	No
63-4 - Odor	MP	Yes	00079434 00111653	No
63-7 - Density, bulk density, or specific gravity	MP	No		Yes
63-12 - pH	MP	No		Yes
63-14 - Oxidizing or reducing action	MP	No		Yes
63-15 - Flammability	MP	No		No[3]/
63-16 - Explodability	MP	No		Yes
63-17 - Storage Stability	MP	Partially	00079434 00111653	Yes

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NORFLURAZON
EPA Reg. No. 11273-10 (97% Technical)

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2]/
§158.120 Product Chemistry (continued)				
63-18 - Viscosity	N/A[5]/	N/A		No[4]/
63-19 - Miscibility	N/A	N/A		No[4]/
Other Requirements				
64-1 - Submittal of Samples	N/A	N/A		No

1/ Composition: MP = Manufacturing-use product.
2/ Data must be submitted no later than six months after receipt of this guidance package.
3/ Only needed for combustible liquids.
4/ Not required because the product is solid at room temperature.
5/ N/A = Not Applicable. Data requirement is not necessary for purposes of this standard.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING NORFLURAZON
EPA Reg. No. 11273-10 (97% Technical)

Data Requirement	Composition[1]/	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.235 Toxicology				
ACUTE TESTING				
81-1 - Oral - Rat	MP	Yes	00111612	No
81-2 - Dermal - Rabbit	MP	Yes	00111612	No
81-3 - Inhalation - Rat	MP	Yes	00112980 00111614	No
81-4 - Primary Eye Irritation - Rabbit	MP	Yes	00091053	No
81-5 - Primary Dermal Irritation - Rabbit	MP	Yes	00111612	No
81-6 - Dermal Sensitization - Guinea Pig	MP	Yes	00111615	No

1/ Composition: MP = Manufacturing-use product.

IV. SUBMISSION OF REVISED LABELING INFORMATION

Note: This section applies to end use products only to the extent described in Section I (Regulatory Position and Rationale). Otherwise, the following information pertains exclusively to manufacturing use products.

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients. Labeling requirements are set out in 40 CFR 162.10 (see Appendix IV-1) and are summarized for products containing this active ingredient as part of this Guidance Document (See Appendix IV-2). Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling information complying with this section and/or Section I, EPA may issue a notice of intent to cancel the registration under FIFRA sec. 6(b)(1).

A. Label Contents

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Appendix IV-2.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is require on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. See Appendix IV-1. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix IV-1. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. See Appendix IV-1. [40 CFR 162.10(f)]

Item 6. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix IV-1. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix IV-1. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix IV-1. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. See Appendix IV-1. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix IV-1. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix IV-1. [40 CFR 162.10 (h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. See Appendix IV-1. [40 CFR 162.10 (h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix IV-1. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C).

c. A "non-flammable aerosol" is one which meets the following criteria:

i. The flame extension is zero inches;

ii. There is no flashback; and

iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "non-flammable (gas, liquid, etc.)" on the label. It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. PRODUCT CLASSIFICATION - Section 3(d) of FIFRA requires that all pesticide formulations/uses be classified for either general or restricted use, and that those uses classified as restricted be limited to use by certified applicators or persons under their direct supervision (or subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses to be restricted, based either on a previous classification determination made through the optional procedures of 40 CFR 162.30 or based on data already available to the Agency, or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you wish to propose that your product should not be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

A. Classification Labeling Requirements

1. All Uses Restricted - Pesticide products bearing directions for use for formulations or uses classified restricted shall bear statements of restricted use classification on the front panel as described below:

a. The statement "RESTRICTED USE PESTICIDE," must appear at the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in 40 CFR 162.10(h)(1)(iv).

b. Directly below this statement on the front panel, a summary statement of the terms of restriction shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some But Not all Uses Restricted - If the Regulatory Position and Rationale states that some uses are classified for restricted use and some uses are unclassified, several courses of action are available:

a. You may label the product for restricted use. If you do so, you may include those uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one containing only unrestricted uses, and the other restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the product names will be assigned separate registration numbers.

B. Compliance Schedules

No product with a use classified for restricted use under this Standard may be released for shipment by the registrant or producer after one year from the date of issuance of this Standard, unless such product bears the restricted use classification. All products still in channels of trade after two years from the date of issuance of this Standard must be labeled for restricted use.

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-4 to determine the disposal instructions appropriate for your products.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix IV-1. [40 CFR 162.10]

B. Collateral Labeling

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Richard F. Mountfort
Product Manager (23)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-1830

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-3 with appropriate attachments.

2. Within 6 months from receipt of this document you must submit:

    a. Confidential Statement of Formula, EPA Form 8570-4.

    b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

    c. Two copies of any required product-specific data.

    d. Two copies of draft labeling, including the label and associated brochures. If current labeling conforms to the requirements of this guidance document and the results of the short-term data, you may submit such labeling. End use product labeling must comply specifically with the instructions in Section II (Regulatory Position and Rationale) of this guidance document. The labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 inch files. The draft label must indicate the intended colors of the final label, clear indication of the front panel label, and the intended type sizes of the text.

    e. Evidence of compliance with data support requirements of FIFRA sec. 3(c)(1)(D). Refer to PR Notice 84-4 (enclosed) for latest requirements.

3. Within the times set forth in Table A, all generic data must be submitted.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager.

Appendix II-1

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

APPENDIX II-2

REGISTRATION STANDARD BIBLIOGRAPHY

Citations Considered to be Part of the Data Base Supporting Registration Under the Norflurazon Standard

00025638 Winkler, V.W.; Patel, J.R. (1980) A 14C-Norflurazon Lactating Goat Study: (I) Absorption, Tissue Distribution and Excretion; (II) Metabolism: Research Report CBK 3029 VWW/JRP 80001. (Unpublished study received Jan 11, 1980 under 9F2177; submitted by Sandoz Corp., Homestead, Fla.; CD:099193-A)

00027375 Sandoz-Wander, Incorporated (1972) Analytical Method # Res-1C: Analysis of Cranberries for Residues of SAN 9789 and its Desmethyl Metabolite, (Unpublished study received Mar 14, 1975, under 11273-EX-9; CDL:224650-I)

00031634 Winkler, V.W.; Januszanis, M.; Seckinges, A.M.; et al. (1980) Norflurazon and Desmethyl norflurazon Residues in Soybeans after Preplant and Pre-emergence Treatment with Zorial: Research Report CBK 3030 VWW 80002. (Unpublished study received Feb 20, 1980, under 11273-13; submitted by Sandoz, Inc. — Crop Protection, San Diego, Calif.; CDL:099332-D)

00031642 Sandoz, Incorporated (19??) Analysis of Norflurazon and Desmethyl norflurazon in Soybean Meal and Oil Fractions. Undated analytical method 2, modification 1. (Unpublished study received Feb 20, 1980 under 11273-13; CDL:099332-H)

00035709 Vilkas, A.G.; Browne, A.M. (1980) The Acute Toxicity of Norflurazon (99.4 Percent Active Ingredient) to the Water Flea, Daphnia magna Straus: UCCES Project No. 11506-16-04. (Unpublished study including letter dated May 20, 1980, from R.J. McCormack to R.E. Stoll, received Jun 5, 1980, under 11273-19; prepared by Union Carbide Corp., submitted by Sandoz, Inc.—Crop Protection, San Diego, Calif.: CDL:242619-A)

00037051 Fink, R. (1972) Final Report: Eight-Day Dietary LC50—Bobwhite Quail: Project No. 620-124. (Unpublished study received on unknown date under 2G1338; prepared by Environmental Sciences Corp., submitted by Sandoz-Wander, Inc., Homestead, Fla.; CDL: 093577-C)

00037052 Freir, L.L.: Finlayson, P.M.; Brady, S.S.; et al. (1972) Results of Tests on the Amount of Residue Remaining, Including a Description of the Analytical Method Used: SAN 97981. (Unpublished study received on unknown date under 2G13381 prepared in cooperation with Washington State Univ. and others; submitted by Sandoz-Wander, Inc., Homestead Fla.; CDL:093577-D)

00037055 Strang, R.H. (1972) A study of the Absorption, Translocation and Metabolism of Two Pyridazinone Herbicides (SAN 6706, SAN 9789) by Cotton, Corn and Soybean. Doctoral dissertation, Louisiana State Univ., Dept. of Plant Pathology. (Unpublished study including submitter summary, received on unknown date under 2G13381 submitted by Sandoz-Wander, Inc., Homestead, Fla,; CD::093577-H)

00039222 Fink, R. (1972) Final Report: One-generation Reproduction Study—Bobwhite Quail: Project No. 620-122. (Unpublished study received Apr 10, 1980, under 11273-19; prepared by Hazleton Laboratories, submitted by Sandoz, Inc.—Crop Protection, San Diego, Calif.; CDL:22197-B)

00041015 WARF Institute, Incorporated (19??) Compound 9789: Two-Year Feeding Study in Mice: Appendix A; Individual Body Weights. Final Report (Unpublished study received Aug 21, 1975, under 4F1506; submitted by Sandoz, Inc., Homestead, Fla.; CDL:0961446-A)

00041016 WARF Institute, Incorporated (19??) Compound 9789: Two Year Feeding Study in Mice: Appendix B: Individual Feed Consumption; Individual Organ Weights; Individual Organ Weight Ratios, Final rept. (Unpublished study received Aug 21, 1975 under 4F1506; submitted by Sandoz, Inc., Homestead, Fla.; CDL 096146-A)

00045704 Bentley, R.E. (1973) Acute Toxicity of San H9789 Technical to Atlantic Oyster (Crassostrea virginica): Report No. FR 74001. Final Rept. (Unpublished study including submitter summary, received May 28, 1980, under 11273-24; prepared by Bionomics, Inc., submitted by Sandoz, Inc.—Crop Protection, San Diego, Calif.; CDL:243090-A)

00047763 Strang, R. H.; Rogers, R. L. (1974) Behavior and Fate of Two Phenyl Pyridazinone Herbicides in Cotton, Corn and Soybean: Report No. FB 74003. Final report. (Unpublished study including submitter summary, received May 13, 1974, under 4F1506; prepared by PPG Industries and Louisiana State Univ., Plant Pathology Dept., submitted by Sandoz, Inc., Homestead, Fla., CDL:094588-B)

00047764 Karapally, J. C. (1974) Metabolism of -3-H-Norflurazon in Cotton, Corn, and Soybean: Report No. JK 74005. Final rept. (Unpublished study received May 13, 1974 under 4F1506; submitted by Sandoz, Inc., Homestead, Fla.; CDL:094588-C)

00047765 Karapally, J. C. (1974) Metabolism of (-3H,-14C)-Norflurazon in Rat: Report No. JK 74007. Final rept. (Unpublished study received May 13, 1974, under 4F1506; submitted by Sandoz, Inc., Homestead, Fla.; CDL:094588-D)

00047766 Karapally, J. C. (1974) Rate of Degradation of -14C-Norflurazon in Soil: Report No. JK 74007. Interim rept. (Unpublished study received May 13, 1974, under 4F1506; submitted by Sandoz, Inc., Homestead, Fla.; CDL:094588-E)

00048362 Fink, R.; Beavers, J. B.; Brown, R. (1980) Final Report: Acute Oral LD_{50}—Mallard Duck: Project No. 131-113. (Unpublished study received Nov. 3, 1980, under 11273-24; prepared by Wildlife International, Ltd.; submitted by Sandoz, Inc., Crop Protection, San Diego, Calif.; CDL:243646-A)

00052172 Fink, R.; (1972) Final Report: One-Generation Reproduction Study—Mallard Ducks: Project No. 620-123. (Unpublished study received Apr. 10, 1980, under 11273-19; prepared by Hazleton Laboratories, submitted by Sandoz, Inc., Crop Protection, San Diego, Calif.; CDL:242197-A)

00063621 Hartman, H. A.; Hrab, R. (1972) Compound 9789: Investigation of Teratogenic Potential in the Rat: Report No. T-1-8/7/72. (Unpublished study received Nov 14, 1972, under 3G1310; submitted by Sandoz, Inc., Homestead, Fla.; CDL: 092234-E)

00063622 Gough, B. J.; Shellenberger, T. E. (1971) Letter sent to Zenas B. Noon, Jr. dated May 18, 1971: Acute toxicological evaluations of San-9789 with fish and wildlife. (Unpublished study received Nov. 14, 1972, under 3G1310; prepared by Gulf South Research Institute, Atchafalaya Basin Laboratories, submitted by Sandoz, Inc., Homestead, Fla.; CDL:092234-F)

00072974 Brusick, D. J. (1977) Mutagenicity Evaluation of Norflurazon: LBI Project No. 2683. Final report. (Unpublished study including submitter summary, received Jun 10, 197, under 11273-10; prepared by Litton Bionetics, Inc., submitted by Sandoz, Inc.—Crop Protection, San Diego, Calif.; CDL:230379-A)

00077292 Fink, R. (1972) Final Report: Eight-Day Dietary LC_{50}—Mallard Ducks: Project No. 620-125. (Unpublished study received Nov. 14, 1972, under 3G1310; prepared by Environmental Sciences Corp., submitted by Sandoz, Inc., Homestead, Fla.; CDL:092234-G)

00079434 Sandoz, Incorporated (19??) Zorial 80 WP Cotton Herbicide, San Diego, Calif.: Sandoz. (Technical bulletin; also In unpublished submission received Jul 2, 1981, under 11273-13; CDL:070190-A)

00079435 Winkler, V.; Patel, J.; Januszanis, M.; et al. (1981) Norflurazon and Desmethyl Norflurazon Residues in Soybeans after Preplant, Preemergence and Split Application Treatments with Zorial: CBK Report #3041-81004. (Unpublished study received Jul 2, 1981, under 11273-13; submtted by Sandoz, Inc.—Crop Protection, San Diego, Calif.; CDL:070190-C)

00080750 WARF Institute, Incorporated (1975) Compound 9789: Reproduction Studies in Rats and Mice: Volume 1: Reproduction Studies on Rats. Final Report. (Unpublished study, including submitter summary, received May 8, 1975, under 5F1602; submitted by Sandoz, Inc., Homestead, Fla.: CDL:094369-A)

00080751 WARF Institute, Incorporated (1975) Compound 9789: Reproduction Studies in Rats and Mice: Volume 2: Reproduction Studies on Mice. Final Report. (Unpublished study, including submitter summary, received May 8, 1975, under 5F1602; submitted by Sandoz, Inc., Homestead, Fla.: CDL:094368-A)

00082019 WARF Institute, Incorporated (1975) Compound 9789: Two-year Feeding Study in Rats. Final Report. (Unpublished study received May 8, 1975, under 5F1602; submitted by Sandoz, Inc., Homestead, Fla.: CDL:094370-A; 094371; 094372; 094373, 094374)

00085081 Winkler, V. K.; Patel, J. R.; Januszanis, M.; et al. (1978?) Determination of Norflurazon Residues in mixed Crop Matrices. Undated method. (Unpublished study received Oct 19, 1981 under 9F2253; submtted by Sandoz, Inc.—Crop Protection, San Diego, Calif.; CDL:070401-B)

00087862 Stoll, R. E.; LeBlanc, G. A.; Sousa, J. V. (1981) Acute LC_{50} Toxicity Study in the Bluegill Sunfish on Norflurazon: EG&G Bionomics No. BK-81-7-897; Sandoz Project T-1638. (Unpublished study received Dec. 18, 1981, under 11273-10; prepared in cooperation with EG&G Bionomics, submitted by Sandoz, Inc.—Crop Protection, San Diego, Calif.; CDL:246430-A)

00087863 Stoll, R. E.; LeBlanc, G. A.; Souse, J. V. (1981) Acute LC_{50}. Toxicity Study in the Rainbow Trout on Norflurazon: EG&G Bionomics No. BK-31-7-899; Sandoz Project T-1637. (Unpublished study received Dec. 18, 1981, under 11273-10; prepared in cooperation with EG & G, Bionomics, submitted by Sandoz, Inc.—Crop Protection, San Diego, Calif.; CDL:246433-A)

00091053 Bukva, N. F. (1970) Final Report—Primary Eye Irritation of Sandoz 9789 Tech. in Rabbits: Contract No. 120-490-7-70. (Unpublished study received Nov 14, 1972 under 3G1310; prepared by Affiliated Medical Enterprises, Inc., submitted by Sandoz, Inc., Homestead, Fla.; CDL:092233-C)

00091055 Fogleman, R. W. (1971) Evaluation of the Subchronic (90-day) Toxicity effects of SAN-9789 in Rats; Contract No. 120-546-9-70. Final rept. (Unpublished study received Nov 14, 1972 under 3G1310; prepared by Affiliate Medical Enterprises, Inc., submitted by Sandoz, Inc., Homestead, Fla.; CDL:092233-F)

00092285 Rogers, R. L. (1971) A Study of the Behavior of H-3 -SAN-6706 and H-3-SAN-9789 in Cotton Plants and Soil: Submitter Report No. FB 72004. (Unpublished study, including submitter summary received Nov 29, 1971, under 3G1310; prepared by Louisiana State Univ., Plant Pathology Dept., submitted by Sandoz, Inc., Homestead, Fla.; CDL:092232-B)

00092290 Sandoz, Inc. (1972?) Mammalian Safety Testing (Unpublished study received on unknown date under 3G1310; CDL:092232-H)

00092294 Sandoz-Wander, Incorporated (1971) Analysis of Cotton Seeds for Residues of SAN 6706, SAN 9789, and Desmethyl SAN 6706. Analytical method # res-1A dated Aug 9, 1971. (Unpublished study received Nov 29, 1971, under 3G1310; CDL:092232-L)

00092296 Sandoz, Incorporated (19??) The Behavior of Seven Chlorinated Insecticides when Analyzed by the Method for Residues of SAN 6706 and its Mono and Desmethyl Metabolites: Research Report No. SanF-0046. (Unpublished study received Nov 29, 1971, under 3G1310; CDL:092232-N)

00092299 Sandoz, Incorporated (1972) Residue Analysis Data Sheet: Cottonseed. (Compilation; unpublished study, including report nos. SanF-0142, SanF-0141, SanF-0143..., received on unknown date under 3G1310; CDL:092232-G)

00092300 Boyd, V. F. (1972) Determination of H-3 SAN 0789 Residues in Whole Non-delinted Cottonseed, and Cottonseed Oil and Meal: Report No. FB 72003. Final report. (Unpublished study received on unknown date under 3G1310, submitted by Sandoz, Inc., Homestead, Fla., CDL:092232-R)

00095845 Yaklich, R. W. (1972) Letter sent to Frank V. Boyd dated Nov 7, 1972. Uptake and translocation of C-14 9789 by the mature cranberry plant. (U.S. Agricultural Research Service, Northeastern Region, New Herbicide Explorations and Chemonarcocide Unit; unpublished study; CDL:093577-I)

00104774 Strang, R. H.; Rogers, R. L. (19??) Preliminary Data on the Absorption, Translocation and Metabolism of SAN-9789 in Cotton, Corn and Soybeans: Submitter Report No. FB 72005. (Unpublished study, including submitter summary, received Nov 29, 1971, under 3G1310; prepared by Louisiana State Univ., Plant Pathology Dept., submitted by Sandoz, Inc., Homestead, Fla.; CDL:092232-C)

00106025 Winkler, V. (1982) Norflurazon and Desmethyl Norflurazon Residues in U.S. Fruit, Nut and Citrus Crops Treated with Solicam: CBK Report #3062/82013 VW. (Unpublished study received Jul 12, 1982, under 11283-19; prepared by Sandoz, Inc., Crop Protection, submitted by General Paint & Chemical Co., Chicago, IL; CDL:247824-A)

00106036 Sandoz, Inc. (1982) Residues of Norflurazon in Pecans and Other Crops. (Compilation; unpublished study received Jul 12, 1982, under 11273-19; CDL:070971-A)

00111607 Heider, J. (1971) 9789-3H, Blood Level, Tissue Distribution and Excretion in the Rat: Report No. P-1-7/7/71. (Unpublished study received Aug 28, 1972, under 3G1310; submitted by Sandoz-Wander, Inc., Homestead, FL; CDL:094124-G)

00111612 Bagdon, R. (1972) Acute Oral Rat Toxicity, Rabbit Eye Irritation and Rabbit Dermal Irritation Studies of Herbicide 9789, 45-511 and a Mixture of 95% 9789:5% 48-511: Report No. T-1-10/24/72. (Unpublished study received May 13, 1974, under 4F1506; prepared by Environmental Sciences Corp., submitted by Sandoz-Wander, Inc., Homestead, FL; CDL:093994-A)

00111614 Klotzsche, C.; Cerioli, A. (1972) Sandoz Herbicide 9789 (Zorial): Two Weeks Subacute Inhalation Toxicity Study in Rats: Baricht Nr. 29/72; Report No. T-1-11/1/72. (Unpublished study received May 13, 1974, under 4F1506; prepared by Sandoz, Switz., submitted by Sandoz-Wander, Inc., Homestead, FL; CDL:093994-C)

00111615 Bagdon, R.; Morelock, J.; Meserve, D. (1973) Guinea Pig Sensitization Test of Herbicide 9789: T-1-5/16/73. (Unpublished study received May 13, 1974, under 4F1506: submitted by Sandoz-Wander, Inc., Homestead, FL; CDL:093994-D)

00111618 Klotzsche, C.; Carpy, S.; De Rijk; et al. (1973) San 9789 (Zorial), 6 Months Feeding Study in Dogs: Bericht Nr. 56/73. (Unpublished study received May 13, 1974, under 4F1506; prepared by Sandoz-Wander, Inc., Homestead, FL; CDL:093995-A)

00111625 Sandoz-Wander, Inc. (1974) Results of Residues Analyses and Description of Methods: Norflurazon. (Compilation; unpublished study received May 13, 1974, under 4F1506; CDL:094004-A)

00111641 Sandoz, Inc. (1976) Residue Chemistry Norflurazon on Selected Fruits & Nuts. (Compilation; unpublished study received Apr. 23, 1976, under 6F1778; CDL:0952230-C)

00111645 Sandoz, Inc. (1977) Summary of Solicam 80WP Herbicide Residue Results. (Compilation; unpublishes study received Mar 14, 1977, under 11273-EX-13; CDL:096039-A)

00111648 Sandoz, Inc. (1978) Residue Chemistry Norflurazon. (Compilation; unpublished study received Mar. 1, 1979, under 11273-19; CDL:0978434-A)

00111649 WARF Institute, Inc. (1975) Compound 9789: Two Year Feeding Study in Mice, Final rept. (Unpublished study received Aug 21, 1975, under 4F1506; submitted by Sandoz-Wander, Inc., Homestead, FL; CDL:096144-A; 096147; 096148)

00111651 Winkler, V.; Madrid, V. (1979) Residue Chemistry: Zorial. (Unpublished study received Mar 30, 1979, under 11273-13; submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:098044-A)

00111653 Sandoz, Inc. (1975) Application for Temporary Permit: Solicam 80WP (Compilation; unpublished study received Mar 14, 1975, under 5G1600; CDL:098180-A)

00111655 Sandoz, Inc. (1974) Residues of Norflurazon in Fruits and Nuts. (Compilation; unpublished study received Mar 14, 1975, under 5G1600; CDL:098180-C)

00111667 Sandoz, Inc. (1975) Residues of Norflurazon in Soybeans and Peanuts Planted as Rotational Crops to Cotton. (Compilation; unpublished study received Oct 15, 1975, under 11273-13; CDL:223878-A)

00111669 Sandoz, Inc. (1977) Norflurazon Residue Determination in Various Products. (Compilation; unpublished study received Jun 20, 1975, under 11273-13; CDL:234222-B)

00112980 Klotzsche, C. (1971) Acute Inhalation Toxicity Study with San 9789, 80% Wettable Powder: Report No. 25/71—Agro. (Unpublished study received Jun 1, 1971, under 11273-EX-2; submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:095046-A)

00118047 LeBlanc, G. (1982) Early Life Stage Toxicity Study in the Fathead Minnow on Norflurazon: Report #BW-82-5-1166; Sandoz Project T-1767. (Unpublished study received Nov 15, 1982 under 11273-13; prepared by EG & G, Bionomics, submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:248828-A)

00118048 LeBlanc, G. (1982) Early Life Stage Toxicity Study in the Rainbow Trout on Norflurazon: Report #BW-82-5-1165: Sandoz Project T-1733. (Unpublished study received Nov 15, 1982 under 11273-13; prepared by EG & G, Bionomics, submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:248829-A)

00118049 LeBlanc,G. (1982) 21-day Chronic Toxicity Test in Daphnia magna: Bionomics Report #BW-82-5-1169; Sandoz Project T-1768. (Unpublished study received Nov 15, 1982 under 11273-13; prepared by EG & G, Bionomics, submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:248830-A)

00128129 Graben, M.; Januszanis, M.; Labriola-Tompkins, E. (1983) Norfluraazon and Desmethyl Norflurazon Residues in Grapes Treated with Solicam: CNK Report 3080/83001. (Unpublished study received Feb 10, 1983 under 11273-19; submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:071403-A)

00131027 Graben, M.; Labriola-Tompkins, E.; Januszanis, M. (1983) Norflurazon and Desmethyl Norflurazon Residues in Florida Citrus Treated with 8 lb ai/a Solicam: CBK Report 3090/83012. (Unpublished study received Aug 30, 1983 under 11273-19; submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:251157-A)

00131151 Hrab, R.; De Raismes, M.; Yao, C. (1983) Dose Range-finding Study of Norflurazon in Pregnant Rabbits: Sandoz Project T-1793. (Unpublished study received Sep 16, 1983 under 11273-13; submitted by Sandoz, Inc., Crop Protection, San Diego, CA; CDL:251278-A)

00131152 Hrab, R.; Halbert, F.; Quagliotti, M.; et al. (1983) Investigation of Teratogenic Potential of Norflurazon in the Rabbit--Segment II: Sandoz Project T-1794. (Unpublished study received Sep 16, 1983 under 11273-13; submitted by Sandoz, Inc., Crop Protection, San Diego; CA; CDL:251279-A)

GS-0229-1 Confidential Statement of Formula (EPA Registration No. 11273-10)

GS-0229-2 Sandoz-Wander Inc. (1976) (Correspondence in EPA Reg. No. 11273-10)

GS-0229-3 SiHig, Marshall (ed.) (1977) Pesticide Process Encyclopedia, Noyes Data Corp. Park Ridge, NJ. p. 351.

GS-0299-4 Sandoz Inc. (1983) Residues from Solicam applications to fruits and nuts prior to January 1978 (from CBK 3014/78001). Supplement 3 to CBK 3080/83001. (Unpublished Summary submitted by Sandoz, Inc. CDL: 071403)

OMB Approval No. 2000-0468 APPENDIX II-3

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. **I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:**

☐ 2. **I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:**

NAME OF OTHER REGISTRANT

☐ 3. **I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:**

☐ 4. **I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):**

☐ 5. **I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)**

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1 (10-82)

APPENDIX II-4

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

Appendix III-1

PRODUCT SPECIFIC DATA REPORT

EPA Registration No.________________ Guidance Document for__________________________

Date__________________________

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID#	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.20 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID#	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral LD-50, rat				
81-2	Acute dermal LD-50				
81-3	Acute inhalation, LC-50 rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

APPENDIX IV-1

§ 162.10 Labeling requirements.

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170–189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

Reproduced from best available copy.

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000.	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive.	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow.

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

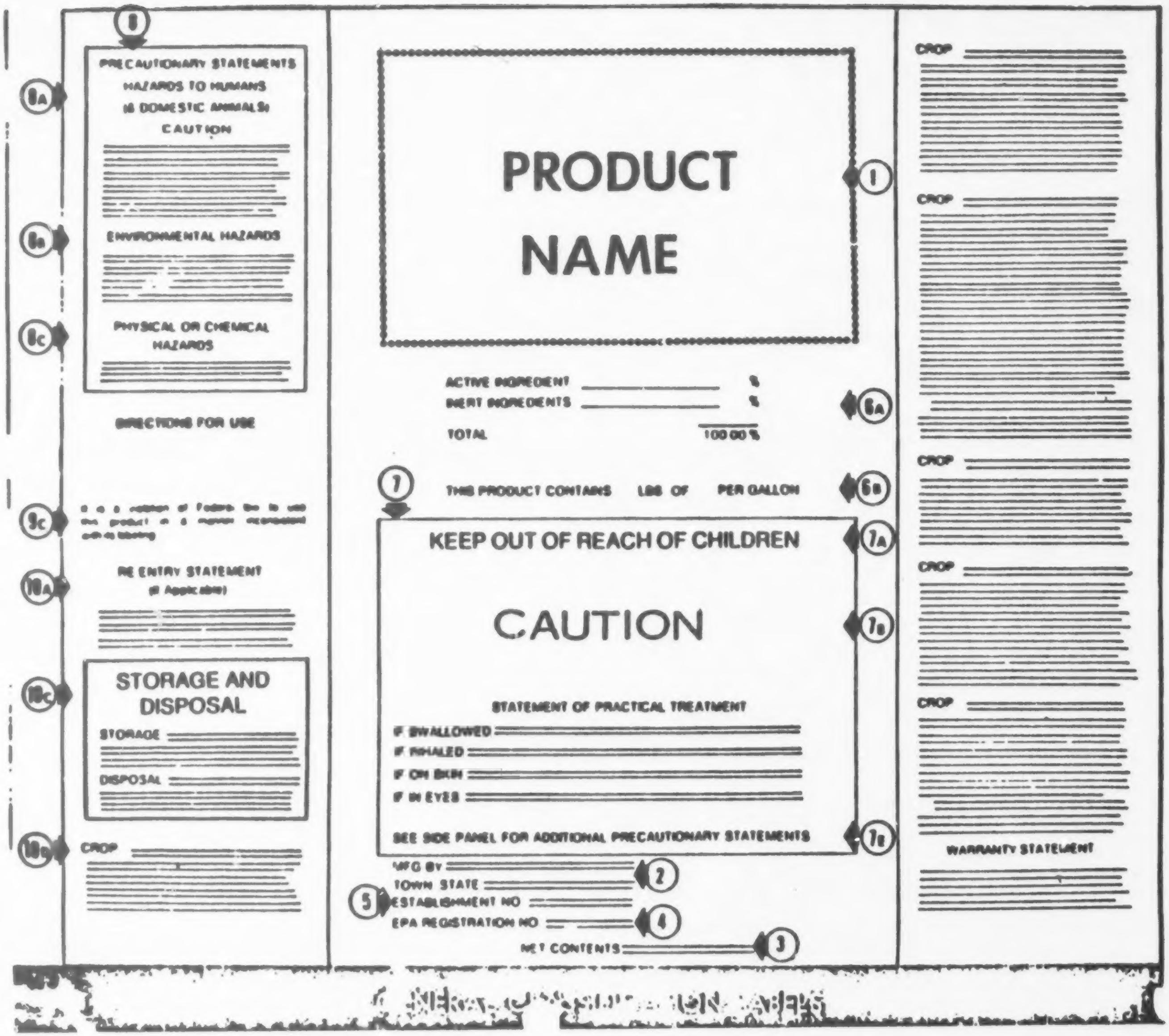
APPENDIX IV-2

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of practical treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse statement	All products	Immediately following statement of classification or ahead of directions for use		
10A	Re-entry statement	All cholinesterase inhibitors	In the directions for use	Immediately after misuse statement	
10C	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use.
10D	Directions for use	All products	None	None	May be in metric as well as U.S. units


⑧
PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
CAUTION
8A
ENVIRONMENTAL HAZARDS
8B
PHYSICAL OR CHEMICAL
HAZARDS
8C
DIRECTIONS FOR USE
9C
RE ENTRY STATEMENT
(if Applicable)
10A
STORAGE AND
DISPOSAL
STORAGE
DISPOSAL
10C
CROP
10D
PRODUCT
NAME
①
ACTIVE INGREDIENT %
INERT INGREDIENTS %
TOTAL 100.00 %
6A
THIS PRODUCT CONTAINS LBS OF PER GALLON
6B
⑦
KEEP OUT OF REACH OF CHILDREN
7A
CAUTION
7B
STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
7E
MFG BY
②
TOWN STATE
⑤
ESTABLISHMENT NO
EPA REGISTRATION NO
④
NET CONTENTS
③
CROP
CROP
CROP
CROP
CROP
WARRANTY STATEMENT

Reproduced from
best available copy.

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

Appendix IV-4

STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

Size of label front panel in square inches	Required type size for the heading STORAGE AND DISPOSAL (all capitals)
10 and under	6 point
Above 10 to 15	8 point
Above 15 to 30	10 point
Over 30	12 point

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

Container Type	Statement
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Appendix IV-4
(continued)

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
    (disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Naphthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List) Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alcohol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
O,O,O,O-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List) Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one
    (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

Appendix IV-4
(continued)

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic anhydride
Methyl alcohol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene